DIA LEARNING

Transitioning Clinical Trials from Directive 2001/20/EC to Regulation (EU) 536/2014 via CTIS

16 February 2024 | 09:00-13:30 CET

Overview

The live virtual training course aims to enhance knowledge in managing transition applications in CTIS.

Legal basis, regulatory and operational aspects of transitions will be explained. Practical case studies to manage the transition in CTIS will be demonstrated.

Participants will have the opportunity to ask questions in order to gain a comprehensive understanding of the CTIS transition activities required for compliance.

Learning Objectives

At the conclusion of this virtual live training course, participants will be able to:

- Recognise the legal and regulatory aspects for transition
- Develop a robust transition implementation strategy
- Identify the transition application dossier components
- Deploy the CTIS transition activities required for compliance

Who Will Attend

This training course is intended for knowledgeable sponsor workspace users (commercial sponsors, academia, CROs), including SMEs wishing to enhance knowledge how to transition ongoing clinical trials authorized under the CT Directive to the EU CT Regulation via CTIS.

Faculty

Pierre-Frederic Omnes
Executive Director, Life Sciences
TransPerfect, France

Ruediger Pankow
Regulatory Affairs Expert, CTIS SME and PO
Germany

Fatima Pimentel
Director, Regulatory Consulting
Syneos Health, Spain

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

16 February 2024

09:00 WELCOME AND INTRODUCTION

09:15 SESSION 1

LEGAL BASE AND REGULATORY ASPECTS

- Clinical trials in scope for transition
- Documentation requirements
- Sources of references and guidance

09:45 SESSION 2

OPERATIONAL ASPECTS

- Timing of transition and planning considerations
- Consolidating versus harmonizing dossier components
- Product cross-reference and “IMPD-Q only” application concept

10:15 SESSION 3

PROCEDURAL ASPECTS

- Master EMA database pre-conditions (IAM, OMS, XEVMPD)
- Expected process (timelines, RFI/responses, substantial modification to complete transition dossier)

10:45 BREAK

11:15 SESSION 4

PRACTICAL CASE STUDIES TO MANAGE THE TRANSITION IN CTIS

- Initial transition application
- Subsequent Substantial Modification (SM)
- IMPD-Q only application scheme

13:30 END OF THE VIRTUAL LIVE TRAINING COURSE

Group Discounts

Register 3 individuals from the same company for the same course and receive complimentary registration for a 4th!*

To take advantage of this offer, please print the registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together via email to basel@diaglobal.org.

**Terms and Conditions apply. Please contact DIA EMEA office for more information.*

Customized Professional Development for Your Team

Get a customized training for your department (or even across different departments!) and benefit from increased:

- Knowledge of a topic of your choice
- Flexibility & Convenience
- Cost Effectiveness

Or explore eLearning to allow self-paced learning.

For more information please contact tereza.krucka@diaglobal.org

About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China

Technical Requirements

To test your system compatibility, please click on the link: https://diaglobal.zoom.us/test

For further information on system requirements, please visit the website:
https://www.diaglobal.org/General/System-Requirements

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 4 credits.

SwAPP

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

REGISTRATION FORM

Transitioning Clinical Trials Virtual Live Training Course # 24532
16 February 2024 | 09:00-13:30 CET

REGISTRATION FEES

Registration fee includes full admission to virtual course, electronic access to training course materials. **Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.** Please check:

FEES	MEMBER EARLY-BIRD valid until 22 Dec 2023	MEMBER valid from 23 Dec 2023	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 450.00 ❑	€ 500.00 ❑	€ 760.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 250.00 ❑	€ 510.00 ❑
A special discount for SMEs on the standard fee is available for a limited number of places. To prove your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA for more information.			

All registration fees are subject to VAT if applicable.

Please enter your company's VAT number: _____

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Payment is due 30 days after registration and must be paid in full by commencement of the course.

DIA MEMBERSHIP

All nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at DIAglobal.org/Membership.

DIA membership will renew automatically at the end of the complimentary membership term, at the then current membership rates. You may cancel automatic membership renewal at any time by accessing your account online at DIAglobal.org. If you would like to decline complimentary membership, please indicate your preference below.

❑ **I would like to decline a one year complimentary DIA membership.**

The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 09:00 and 17:00 CE(S)T. **Tel.** :+41 61 225 51 51

Email: **Basel@DIAglobal.org** **Mail:** DIA, Küchengasse 16, 4051 Basel, Switzerland
Web: **www.DIAglobal.org**

TERMS AND CONDITIONS

Cancellation Policy
All cancellations must be made in writing and be received at the DIA office four weeks prior to the event start date. Cancellations are subject to an administrative fee:
- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.

DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy
You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA office of any such substitutions as soon as possible.

Event Stream and Recording
If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click https://www.diaglobal.org/general/photography-policy.

Privacy Policy
DIA respects the privacy of all of its members and customers. To view our privacy policy, click https://www.diaglobal.org/about-us/privacy-policy.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number

Attendee email required for course material access

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N° | | | | | | | | | | | | | | | | |

Exp. Date | | / | |

Cardholder's Name

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Course ID #24532 as well as the invoice number to ensure correct allocation of your payment.
Please note: if you register 7 days or less before the start of the course, it is not possible to settle the registration fee by bank transfer, but only by credit card. Thank you for your understanding and cooperation.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on http://www.diaglobal.org/EUTerms

Date	Signature